

Exhibit J

85 FR 35100-01, 2020 WL 3050467(F.R.)
NOTICES
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of the Secretary

Second Amendment to Declaration Under the Public Readiness and
Emergency Preparedness Act for Medical Countermeasures Against COVID-19

Monday, June 8, 2020

***35100** ACTION: Notice of amendment.

SUMMARY: The Secretary issues this amendment pursuant to section 319F-3 of the Public Health Service Act to clarify that Covered Countermeasures ***35101** under the Declaration include qualified pandemic and epidemic products that limit the harm COVID-19 might otherwise cause.

DATES: This amendment to the Declaration as published on March 17, 2020 ([85 FR 15198](#)) was effective as of February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202-205-2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from, the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving “willful misconduct” as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant. The PREP Act was enacted on December 30, 2005, as [Public Law 109-148](#), Division C, § 2. It amended the Public Health Service (PHS) Act, adding section 319F-3, which addresses liability immunity, and section 319F-4, which creates a compensation program. These sections are codified at [42 U.S.C. 247d-6d](#) and [42 U.S.C. 247d-6e](#), respectively. Section 319F-3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), [Public Law 113-5](#), enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, [Public Law 116-136](#), enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the Secretary declared a public health emergency pursuant to section 319 of the PHS Act, [42 U.S.C. 247d](#), effective January 27, 2020, for the entire United States to aid in the response of the nation's health care community to the COVID-19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that Declaration on April 26, 2020. On March 10, 2020, the Secretary issued a [Declaration under the PREP Act for medical countermeasures against COVID-19 \(85 FR 15198, Mar. 17, 2020\)](#). On April 10, the Secretary amended the March 10, 2020 Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act ([85 FR 21012, Apr. 15, 2020](#)).

The Secretary now amends the March 10, 2020, Declaration to clarify that covered countermeasures under the Declaration include qualified products that limit the harm COVID-19 might otherwise cause. [42 U.S.C. 247d-6d\(i\)\(7\)\(A\)\(i\)\(II\)](#). This amendment is made in accordance with section 319F-3(b)(4) of the PHS Act, which authorizes the Secretary to amend a PREP Act Declaration at any time.

Description of This Amendment by Section

Section VI. Covered Countermeasures

Section VI of the Declaration identifies the Covered Countermeasures for which the Secretary has recommended activities under section III of the Declaration. The PREP Act, as amended, states that a “Covered Countermeasure” must be a “qualified pandemic or epidemic product,” a “security countermeasure,” a drug, biological product, or device authorized for emergency use in accordance with sections 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act, or a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

As described in section VI of the preamble to the March 10, 2020 Declaration, the PREP Act further defines a “qualified pandemic or epidemic product” to mean a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that is (i) manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; or (iii) a product or technology intended to enhance the use or effect of such a drug, biological product, or device. A qualified pandemic or epidemic product must also be approved, cleared, licensed, or authorized for investigational or emergency use under the FD&C Act or PHS Act. The Coronavirus Aid, Relief, and Economic Security (CARES) Act section 3103, [Public Law 116-136](#) (Mar. 27, 2020), amended the PREP Act to add respiratory protective devices to the list of covered countermeasures so long as they are NIOSH approved and determined by the Secretary to be a priority for use during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act. [85 FR 21012](#) (Apr. 15, 2020) (amending the Declaration effective March 27, 2020 to address this statutory change).

The Secretary intended section VI of the March 10, 2020 Declaration to include all qualified pandemic and epidemic products defined under the PREP Act and described in the preamble to the Declaration. But section VI of the March 10, 2020 Declaration identified Covered Countermeasures under the Declaration as “any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.” [85 FR 15202](#). That description omitted the phrase from the statutory definition that qualified pandemic and epidemic products may also include products that “limit the harm such a pandemic or epidemic might otherwise cause.” The Secretary intended to identify the full range of qualified countermeasures in the March 10, 2020 Declaration. The Secretary accordingly amends section VI of the Declaration to clarify that intent.

Qualified pandemic and epidemic products that limit the harm that COVID-19 might otherwise cause are those that would not have been manufactured, administered, used, designed, developed, modified, licensed, or procured but for the COVID-19 pandemic, even when the products are manufactured, administered, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure health threats or conditions other than COVID-19. For example, the COVID-19 pandemic has resulted in shortages of certain drugs and devices that the FDA has authorized. These drugs and devices may be used for COVID-19 and other health conditions. Those shortages are “harm[s] [COVID-19] might otherwise cause.” Filling those shortages caused by COVID-19 reduces the strain on the American healthcare system by mitigating the escalation of adverse ***35102** health conditions from COVID-19 and non-COVID-19 causes. And mitigating that escalation conserves limited healthcare resources—from personal protective equipment to healthcare providers—which are essential in the whole-of-Nation response to the COVID-19 pandemic.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID-19.

Section VI of the March 10, 2020, Declaration under the PREP Act for medical countermeasures against COVID-19, as amended April 10, 2020, is further amended pursuant to section 319F-3(b)(4) of the PHS Act, as described below. All other sections of the Declaration remain in effect as published at [85 FR 15198 \(Mar. 17, 2020\)](#) and amended at [85 FR 21012 \(Apr. 15, 2020\)](#).

Covered Countermeasures, section VI, delete in full and replace with:

VI. Covered Countermeasures

[42 U.S.C. 247d-6b\(c\)\(1\)\(B\)](#), [42 U.S.C. 247d-6d\(i\)\(1\)](#) and (7)

Covered Countermeasures are

(1) any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used

a. to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or

b. to limit the harm that COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, might otherwise cause; or

(2) any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be “qualified pandemic or epidemic products,” or “security countermeasures,” or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act, or a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

Authority: [42 U.S.C. 247d-6d](#).

Dated: June 4, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020-12465 Filed 6-4-20; 4:15 pm]

BILLING CODE 4150-28-P

End of Document

© 2020 Thomson Reuters. No claim to original U.S. Government Works.